The rejection based on double patenting is moot as the involved claims are canceled.

Claims 1-10, 17-19 and amended claims 21-35 and new claims 38-41 are submitted for the Examiner's reconsideration.

Attached is a copy of the version of the amended claim 21 showing the changes.

Claim 21 is amended to correct for a minor informality. The claim originally called for a spaced unit form, whereas the term "unit form" is intended to refer to the deposited dosage and substrate. Therefore this term is amended in the interest of clarity and consistency. Also, the claim is amended to refer to the deposited dosage unit is being in discrete locations as claimed in others of the claims. This claim is not amended to overcome the prior art.

The claims are rejected under 35 U.S.C. §103 as being unpatentable over Mlodozeniec. Applicant appreciates the Examiner's careful thought in formulating the rejection. However, such a rejection is incorrect as a matter of law. This was discussed in detail in applicants' prior response and is repeated herein.

Claim 1 calls for:

> said at least one active ingredient being deposited <u>in separate discrete spaced locations on the substrate</u>, each location comprising the active ingredient present in each of the unit forms in an amount which does not vary from a predetermined target amount by more than about 5 weight per cent. (underlining added)

Mlodozeniec does not provide an enabling teaching or disclosure of this subject matter especially the underlined portion. "To be prior art under section 102(b), the reference must put the anticipating subject matter at issue into the possession of the public through an <u>enabling</u> disclosure." *Chester v. Miller*, 906 F.2d 1574, 1577 n.2, 15 USPQ2d 1333, 1336, n.2 (Fed. Cir. 1990) (emphasis added), citing *In re Donohue,* 226

uspq 619 (Fed. Cir. 1985) and *In re LeGrice*, 133 USPQ 365 (CCPA 1962). The court in *In re Donohue* states that "It is well settled that prior art under 35 U.S.C. §102 must sufficiently describe the claimed invention to have placed the public in possession of it." Further, the court states Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art, if it was not enabling."

Plainly, whether a reference is cited as anticipating or as suggesting, is a difference without substance, if it is the only reference being cited. If a reference is not enabling as to the structure that is being suggested, it is not prior art, whether the issue is §102 or §103.

Mlodozeniec not only fails to enable, but actually teaches away from, the claims.

Mlodozeniec discloses electrostatic deposition of charged pharmaceutical powder onto a moving web. The web is continuously fed along a charged metal surface, and thus moves through a chamber containing a cloud of charged particles. See Fig. 2 and col. 17, lines 30-37. Mlodozeniec regulates the amount of the dosage by varying the feed rate of the charged powder (but not the feed rate of the web) into the deposition chamber. See col. 15, lines 34-41. His purpose in doing this is "to provide a uniformity of flow in order to enable exact and uniform deposition of the active ingredient on the web." See col. 10, lines 66-68 (reference omitted). However the entire web is coated in a film of the active ingredient and not in spaced discrete locations as claimed. For example, this is different than that claimed in claim 1, as underlined above, claim 6, "forming a plurality of discrete spaced . . . dosage forms on a substrate," claim 17, "each unit form of the second plurality being deposited in spaced relation to the other unit forms of the second plurality on a substrate," and claim 21, "forming a self contained complete single spaced discrete unit as deposited," for example. The deposition must be in such spaced discrete locations while the deposition maintains the "accuracy of the active ingredient present in each of the unit forms [is] in an amount which does not vary from a predetermined target amount by more than about 5 weight

per cent." (claim 1, for example). This Mlodozeniec does not do. There is no structure in Mlodozeniec that discloses an apparatus that can perform such deposition in separate discrete locations as claimed.

Mlodozeniec, at col. 26, lines 39-59, discloses a potential alternate embodiment. That is, instead of continuously feeding the web through the particle deposition chamber, the active ingredient could be deposited at "short intervals," with the result that the active ingredient could be "spot deposited" and surrounded on all sides by uncoated webs. However, Mlodozeniec admits, in the middle of the disclosure cited, that such "spot deposits" would not provide a "therapeutically efficacious dosage." In Mlodozeniec's own words: "In view of the [shortcomings of his equipment and of his disclosed method], it is preferred to load active substance continuously onto the web in sufficient amount so that the unitizing operation produces dosage forms containing a therapeutically efficacious dosage." See col. 26, lines 48- 54 (emphasis added).

That is, by starting and stopping the movement of the web through the particle-filled deposition chamber, Mlodozeniec could make "spot deposits," but he then would lose the control normally afforded by the continuous movement of the web. Thus, there would be no way for Mlodozeniec to ensure that each of the spot deposits contained the correct amount of drug. Such "spot deposits" certainly would not meet the limitation of the claims , wherein "the active ingredient in each deposition is present in an amount that does not vary from a target amount by more than about 5 weight percent. (emphasis added)"

Applicant can find no disclosure in Mlodozeniec of equipment or process conditions that would enable the production of "spot deposits" containing a therapeutically efficacious "target amount" of active ingredient. In view of such non-enablement, Mlodozeniec fails as prior art under §102 and §103. *Chester v. Miller, supra*.

Moreover, Mlodozeniec teaches that, in order to obtain a therapeutically efficacious dosage amount, his method could not be performed at "short intervals," but

instead would have to be performed continuously. This would result in a "uniform deposition" across the web, which then would need to be "unitized" (that is, sliced, diced and/or folded) according to Mlodozeniec's central teaching. ("While the methods and equipment . . . may vary somewhat, the overall prime object is uniformity of deposition, i.e. to deposit active ingredient on the moving web surfaces in an exceptionally uniform manner." See col. 15, lines 64-68 (emphasis added).)

The deposition as claimed in claim 1 for example calls for the deposition to be made "in separate discrete spaced locations on the substrate. This is distinguishable from the Mlodozeniec deposition which would result in a "uniform deposition" across the web, not in discrete spots corresponding to each dosage as claimed, which web deposition then would need to be "unitized" (that is, sliced, diced and/or folded) according to Mlodozeniec's central teaching. Such dicing is foreign to what is claimed and can introduce its own inaccuracies not addressed by Mlodozeniec. Mlodozeniec is silent as to what is claimed in claim 1 as discussed. Mlodozeniec, teaches away, and by teaching away from forming a dosage unit by "spot deposits," and having no supporting disclosure for apparatus to do this deposition to the accuracy as claimed, is not prior art under 35 :USC §102 and §103. For these reasons, claim 1 is believed allowable.

Claim 6 calls for:

> forming a plurality of discrete spaced discrete pharmaceutical or diagnostic unit dosage forms on a substrate

This claim is believed allowable since Mlodozeniec is non-enabling for this step as discussed above. Mlodozeniec does not form or suggest how to so form a plurality of discrete spaced discrete pharmaceutical or diagnostic unit dosage forms on a substrate to the claimed accuracy. The dosage forms are not spaced or discrete, but

are fungible as one continuous layer and must be mechanically unitized by other apparatus. Once unitized, they no longer are spaced on a substrate, but are formed into different unitized substrates and not "a substrate" as claimed. See MPEP 2164.01(b) citing *In re Ghiron* wherein Mlodozeniec does not disclose such an apparatus and teaches away as discussed above. If formed as separate "spots," Mlodozeniec disclaims the claimed accuracy in such depositions. This is non-enabling as to this aspect of this claim and Mlodozeniec is not a proper reference.

Claim 17 calls for:

> each unit form of the second plurality being deposited in spaced relation to the other unit forms of the second plurality on a substrate

This claim is believed allowable since the Mlodozeniec is non-enabling for this aspect of claim 17 as discussed.

Claim 21 calls for:

> a first deposit, including an active ingredient deposited on a first surface of said first base substrate film and forming a self contained complete single discrete unit as deposited; *(underlining added)

The Mlodozeniec reference does not disclose, teach or suggest this structure since an effective single dosage unit can not be formed as an effective self contained complete single unit form as deposited for the reasons discussed above. This reference requires depositing a continuous layer and then dicing the layer. Mlodozeniec does not suggest claim 21 which is different. Claim 21 is believed allowable.

The remaining claims of claims 1-34 depend from the independent claims and are believed allowable at least for the same reasons.

Claims 38-41 correspond somewhat to dependent claim 33 and are presented separately. Claims 38 to 41 further distinguish over Mlodozeniec. These claims are

directed to the subject matter claimed in dependent claims 33 to 35, depending upon claim 21, and include the following:

- independent claims 38 and 40 incorporate the structures recited in original base claim 21;
- claims 38 to 41 include structure directed to a "pharmaceutical unit dosage form," instead of a "pharmaceutical or diagnostic unit form"; and
- claims 38 to 41 call for "said second active ingredient is different from said first active ingredient."

The claimed subject matter of claims 38-41 relates to unit dosage forms that may include more than one active ingredient. In contrast, Mlodozeniec coats his web with only one active ingredient. At col. 23, line 52 through col. 24, line 52, Mlodozeniec discloses a "fan-folding" fabrication technique, wherein his active-ingredient-coated-web is folded over on itself, resulting in a dosage form containing multiple layers of the same active ingredient. Mlodozeniec fails to suggest, much less enable, the deposition of a second active ingredient that is different from the first active ingredient. Therefore, claims 38 to 41 distinguish patentably over Mlodozeniec.

For these reasons claims 1-10, 17-19, 21-35 and 38-41 are believed allowable. Since all of the claims have been shown to be in proper form for allowance, such action is respectfully requested.

Enclosed is a separate letter showing the fee calculation for the added two independent claims and a check in the amount of $204.00 for the fee for the added claims.

The Commissioner is authorized to charge or credit deposit account 03-0678 for any under or overpayments in connection with this paper.

Respectfully submitted,
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I hereby certify that this correspondence is being deposited on the below noted date with the U.S. Postal Service as First Class Mail, postage prepaid, in an envelope addressed to:
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_____
William Squire
Date: October 25, 2002

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VERSION SHOWING THE CHANGES TO THE CLAIMS

21 (Twice amended). A product comprising a pharmaceutical or diagnostic unit form, the unit form comprising:

a first base substrate film comprising a first polymer;

a first deposit, including an active ingredient deposited on a first surface of said first base substrate film and forming a self contained complete single spaced discrete unit [form] as deposited; and

a cover substrate film comprising a second polymer, the cover substrate film covering the first deposit and joined to said first base substrate film by a first bond that surrounds said deposit, said active ingredient being present in an amount that does not vary from a target amount by more than 5 weight per cent.